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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,292	11/15/2001	Brian Ward	SGM 6938.1	2146
321	7590	01/16/2004	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			HORLICK, KENNETH R	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,292

Applicant(s)

WARD ET AL.

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/22/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-158 is/are pending in the application.
- 4a) Of the above claim(s) 1-45,89-135 and 155-158 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46,48,50-88 and 136-154 is/are rejected.
- 7) ☒ Claim(s) 47 and 49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 (5 pages)
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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1. Applicant's election with traverse of Group II in the paper filed 10/22/03 is acknowledged. The traversal is on the ground(s) that the three Groups of inventions are related, and that a search of any one of the Groups is coextensive with a search of any one of the other groups. This is not found persuasive because: 1) although Groups I/III and I/II are related, the traversal does not point out why distinctness as described in the restriction requirement is in error; and 2) the Office disagrees that searches for any one of the inventions would be coextensive with searches for the others. Distinct method and product claims require separate considerations and non-overlapping searches, and as noted above the traversal does not point out any errors in the finding of distinctness among the three inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 48 and 61-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 48 is confusing because the inclusive language "and" is used with the recited group of epitope tags while it would appear that the alternative language "or" is intended. Clarification is required.

B) Claims 61-73 are confusing because "dNTP<sub>1</sub>" lacks proper antecedent basis in claim 46. Correction is required.

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46, 50-88, and 136-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsay Shaw et al. (US 5,683,869).

These claims are drawn to kits comprising a dNTP mixture, wherein said mixture comprises at least one modified nucleotide which when incorporated into a polynucleotide imparts exonuclease resistance (claim 46 and dependent claims); or wherein said mixture comprises modified dNTPs for at least two of the four nucleotide triphosphates, wherein said modified dNTPs comprise alpha phosphate modified bases (claim 136 and dependent claims).

As an initial matter, it is noted that in kit claims written instructions and other "intended use"-type limitations are not given patentable weight.

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Ramsay Shaw et al. disclose methods comprising the use of a dNTP mixture comprising at least one modified nucleotide, said nucleotide conferring exonuclease resistance when incorporated into a polynucleotide. Said methods include the use of the enzyme exonuclease III. Some of the dNTP mixtures comprise two or three such modified nucleotides. In column 1, prior art is cited teaching that such dNTP mixtures comprising 5-alpha thio-modified dNTPs were known in the art, and the main disclosure relates to 5-alpha borano-modified dNTPs. See columns 1-10, 15, 17-19, and example 7 in columns 24-25.

Ramsay Shaw et al. do not disclose kits comprising said dNTP mixtures.

Combination of reagents into kits for the convenience of practicing methods which require such reagents was indisputably well known and common knowledge in the art at the time of the invention.

One of ordinary skill in the art would have been motivated to make kits comprising various dNTP mixtures comprising modified dNTPs capable of conferring exonuclease resistance to polynucleotides (such as alpha-thio or alpha-borano-modified dNTPs) because such kits would have clearly been useful in carrying out the methods of Ramsay Shaw et al. It is emphasized that any differences between the method of Ramsay Shaw et al. and that of the instant disclosure are not relevant here because the claims in question are kit claims, and any motivation found in the prior art for making a claimed kit is applicable, even if for a different purpose. As far as the claims requiring various concentrations of modified versus unmodified dNTPs, this is considered to be routine optimization of reaction parameters, which is understood not to contribute to

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unobviousness in the absence of evidence to the contrary. Besides, Example 2 in columns 17-19 teaches optimization of modified dNTP incorporation using kinetic analysis, including considerations of the ratio between modified/unmodified dNTPs. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

4. Claims 46, 50, and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 5,455,166).

Walker discloses a method comprising the use of a dNTP mixture comprising at least one modified nucleotide, said nucleotide conferring nuclease resistance when incorporated into a polynucleotide. Said modified nucleotides are alpha-thio dNTPs. See especially columns 6-7 and 10-12.

Walker does not disclose kits comprising said dNTP mixtures.

Combination of reagents into kits for the convenience of practicing methods which require such reagents was indisputably well known and common knowledge in the art at the time of the invention.

One of ordinary skill in the art would have been motivated to make kits comprising various dNTP mixtures comprising modified dNTPs capable of conferring nuclease resistance to polynucleotides (such as alpha-thio-modified dNTPs) because such kits would have clearly been useful in carrying out the method of Walker. It is emphasized that any differences between the method of Walker and that of the instant disclosure are not relevant here because the claims in question are kit claims, and any

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motivation found in the prior art for making a claimed kit is applicable, even if for a different purpose. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

5. Claims 47 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 48 is free of the prior art but is rejected for other reasons. No prior art has been found teaching or suggesting a kit comprising a dNTP mixture as discussed above and in addition an adaptor sequence encoding at least one epitope tag.

6. No claims are allowable.

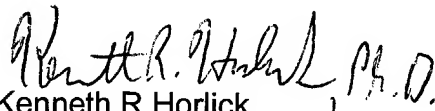
7. Schmidt et al. (US 6,270,976) is made of record as a reference of interest.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905 (571-272-0784 after 01/22/04). The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Kenneth R Horlick  
Primary Examiner  
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01/12/04